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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,397	01/26/2001	Karlheinz Drauz	201554US0X	4705

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EXAMINER
KIM, SUN U

ART UNIT	PAPER NUMBER
1723	6

DATE MAILED: 06/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/769,397	Drauz et al.
Examiner	**Art Unit**
John Kim	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 26, 2001* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) *9-23* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to an amino acid composition, classified in class 424, subclass 9.351.

II. Claim 9, drawn to a method of preparing a dialyzer fluid, classified in class 137, subclass 86.

III. Claims 10-12, drawn to a method of hemodialysis, classified in class 210, subclass 646.

IV. Claims 13-23, drawn to an apparatus for hemodialysis with a dialyzer, classified in class 210, subclass 252.

2. The inventions are distinct, each from the other because of the following reasons: Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(I)).

3. Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice filtering fluid.

4. Inventions I or II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions since Invention I is a dialysis fluid composition and II is a method of making a dialyzer fluid and Invention IV is an apparatus for hemodialysis.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Mr. James Kelly on 6/26/02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe what is the basis of weight that claimed amino acids proportions are based on. Are the weight proportions of amino acids based on total weight of amino acids or are the weight proportions based on total weight of hemodialysis fluid components including weights of amino acids.

12.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite for failing to particularly point out whether the weight

proportions of amino acids are based on total weight of amino acids or whether the weight proportions of amino acids are based on total weight of hemodialysis fluid components including weights of amino acids.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over The International Journal of Artificial Organs, Vol. 1, No. 1, 1978, pages 112-113 (hereinafter referred to as Quarto di Palo et al) in view of the admitted prior art (see Table 5 on page 9-10 of the specification). JK 8/21/02 Quarto de Palo et al teach that amino acids were added to the dialysis solution in a concentration equal to that of normal plasma and treating patients with above concentrations of amino acids in normal plasma resulted in prevention of amino acid loss during hemodialysis, restoration of the pathologically decreased values and removal of the amino acids present in blood in increased concentrations (see page 112). 8/4/02 JK Furthermore, Quarto de Palo et al teach that administering amino acids in the right proportions and at the most favorable time i.e. during dialysis, they expected a greater utilization of amino acids for protein synthesis than for energy purpose (see page 112). 8/4/02 JK Claims 1-8 essentially differ from the dialyzer fluid comprising the claimed amino acid concentrations in its claimed proportions. Specification teaches that the amino acid

concentrations occurring in the plasma of a healthy person are set forth in Table 5 of the pages 9-10 of the specification which are within the claimed amino acid concentrations in a dialyzer fluid as claimed in claims 7-8.. It would have been obvious to a person of ordinary skill in the art to modify the dialyzer fluid of Quarto di Palo et al to arrive at the claimed proportions of amino acids in the dialyzer fluid with known information of the amino acid concentrations occurring in the plasma of a healthy person to provide the improved advantages in prevention of amino acid loss during hemodialysis, restoration of the pathologically decreased values and removal of the amino acids present in blood in increased concentrations.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,670,176 teaches amino acid solutions for treatment of peritoneal dialysis solution.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim
Primary Examiner
Art Unit 1723

J. Kim
June 26, 2002